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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,709	09/27/2002	Sheena M. Loosmore	1038-1138 MIS:jb	5961

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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 10/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/806,709	LOOSMORE ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group A, claim(s) 1-11 and 13-15 are drawn to a nucleic acid and vector comprising a promoter coupled to a modified operon comprising SEQ ID NO:27 or 28.

Group B, claim(s) 1-11 and 13-15 are drawn to a nucleic acid and vector comprising a promoter coupled to a modified operon comprising SEQ ID NO:31 or 32.

Group C, claim(s) 1-11 and 13-15 are drawn to a nucleic acid and vector comprising a promoter coupled to a modified operon comprising SEQ ID NO:36 or 37.

Group D, claim(s) 1-11 and 13-15 are drawn to a nucleic acid vector comprising a promoter coupled to a modified operon comprising SEQ ID NO:40 or 41.

Group E, claim(s) 1-11 and 13-15 are drawn to a nucleic acid and vector comprising a promoter coupled to a modified operon comprising SEQ ID NO:44 or 45.

Group F, claim(s) 1-11 and 13-15 are drawn to a nucleic acid and vector comprising a promoter coupled to a modified operon comprising SEQ ID NO:48 or 49.

Group G, claim(s) 1-11 and 13-15 are drawn to a nucleic acid and vector comprising a promoter coupled to a modified operon comprising SEQ ID NO:52 or 53.

Group H, claim(s) 1-11 and 13-15 are drawn to a nucleic acid and vector comprising a promoter coupled to a modified operon comprising SEQ ID NO:56 or 57.

Group I, claim(s) 1-11 and 13-15 are drawn to a nucleic acid an vector comprising a promoter coupled to a modified operon comprising SEQ ID NO:60 or 61.

Group J, claim(s) 1-11 and 13-15 are drawn to a nucleic acid and vector comprising a promoter coupled to a modified operon comprising SEQ ID NO:64 or 65.

Group K, claim(s) 1-11 and 13-15 are drawn to a nucleic acid and vector comprising a promoter coupled to a modified operon comprising SEQ ID NO:68 or 69.

Group L, claim(s) 1-11 and 13-15 are drawn to a nucleic acid and vector comprising a promoter coupled to a modified operon comprising SEQ ID NO:72 or 73.

Group M, claim 12 is drawn to a nucleic acid molecule encoding a high molecular weight (HMW) protein comprising SEQ ID NO:25 or 26.

Group N, claim 12 is drawn to a nucleic acid molecule encoding a high molecular weight (HMW) protein comprising SEQ ID NO:27 or 28.

Group O, claim 12 is drawn to a nucleic acid molecule encoding a high molecular weight (HMW) protein comprising SEQ ID NO:29 or 30.

Group P, claim 12 is drawn to a nucleic acid molecule encoding a high molecular weight (HMW) protein comprising SEQ ID NO:31 or 32.

Group Q, claim 12 is drawn to a nucleic acid molecule encoding a high molecular weight (HMW) protein comprising SEQ ID NO:33 or 34.

Group R, claim 12 is drawn to a nucleic acid molecule encoding a high molecular weight (HMW) protein comprising SEQ ID NO:35 or 36.

Group S, claim 12 is drawn to a nucleic acid molecule encoding a high molecular weight (HMW) protein comprising SEQ ID NO:37 or 38.

Group T, claim 12 is drawn to a nucleic acid molecule encoding a high molecular weight (HMW) protein comprising SEQ ID NO:39 or 40.

Group U, claim 12 is drawn to a nucleic acid molecule encoding a high molecular weight (HMW) protein comprising SEQ ID NO:41 or 42.

Group V, claim 12 is drawn to a nucleic acid molecule encoding a high molecular weight (HMW) protein comprising SEQ ID NO:43 or 44.

Group W, claim 12 is drawn to a nucleic acid molecule encoding a high molecular weight (HMW) protein comprising SEQ ID NO:45 or 46.

Group X, claim 12 is drawn to a nucleic acid molecule encoding a high molecular weight (HMW) protein comprising SEQ ID NO:47 or 48.
Group Y, claim 12 is drawn to a nucleic acid molecule encoding a high molecular weight (HMW) protein comprising SEQ ID NO:49 or 50.

Group Z, claim 12 is drawn to a nucleic acid molecule encoding a high molecular weight (HMW) protein comprising SEQ ID NO:51 or 52.

Group AA, claim 12 is drawn to a nucleic acid molecule encoding a high molecular weight (HMW) protein comprising SEQ ID NO:53 or 54.

Group BB, claim 12 is drawn to a nucleic acid molecule encoding a high molecular weight (HMW) protein comprising SEQ ID NO: 55 or 56.

Group CC, claim 12 is drawn to a nucleic acid molecule encoding a high molecular weight (HMW) protein comprising SEQ ID NO:57 or 58.

Group DD, claim 12 is drawn to a nucleic acid molecule encoding a high molecular weight (HMW) protein comprising SEQ ID NO:59 or 60.

Group EE, claim 12 is drawn to a nucleic acid molecule encoding a high molecular weight (HMW) protein comprising SEQ ID NO:61 or 62.

Group FF, claim 12 is drawn to a nucleic acid molecule encoding a high molecular weight (HMW) protein comprising SEQ ID NO:63 or 64.

Group GG, claim 12 is drawn to a nucleic acid molecule encoding a high molecular weight (HMW) protein comprising SEQ ID NO:65.

Group HH, claim(s) 18-20 are drawn to a plasmid vector.

Group II, claims 21 and 23-24 are to an isolated and purified protective HMW1 protein comprising SEQ ID NO:28.

Group JJ, claims 21 and 23-24 are to an isolated and purified protective HMW1 protein comprising SEQ ID NO:32.

Group KK, claims 21 and 23-24 are to an isolated and purified protective HMW1 protein comprising SEQ ID NO:37.

Group LL, claims 21 and 23-24 are to an isolated and purified protective HMW1 protein comprising SEQ ID NO:41.

Group MM, claims 21 and 23-24 are to an isolated and purified protective HMW1 protein comprising SEQ ID NO:45.

Group NN, claims 21 and 23-24 are to an isolated and purified protective HMW1 protein comprising SEQ ID NO:45.

Group OO, claims 21 and 23-24 are to an isolated and purified protective HMW1 protein comprising SEQ ID NO:49.

Group PP, claims 21 and 23-24 are to an isolated and purified protective HMW1 protein comprising SEQ ID NO:53.

Group QQ, claims 21 and 23-24 are to an isolated and purified protective HMW1 protein comprising SEQ ID NO:57.

Group RR, claims 21 and 23-24 are to an isolated and purified protective HMW1 protein comprising SEQ ID NO:61.

Group SS, claims 21 and 23-24 are to an isolated and purified protective HMW1 protein comprising SEQ ID NO:65.

Group TT, claims 21 and 23-24 are to an isolated and purified protective HMW1 protein comprising SEQ ID NO:69.

Group UU, claims 21 and 23-24 are to an isolated and purified protective HMW1 protein comprising SEQ ID NO:73.

Group VV, claims 21 and 23-24 are to an isolated and purified protective HMW2 protein comprising SEQ ID NO:28.

Group WW, claims 21 and 23-24 are to an isolated and purified protective HMW2 protein comprising SEQ ID NO:32.

Group XX, claims 21 and 23-24 are to an isolated and purified protective HMW2 protein comprising SEQ ID NO:37.

Group YY, claims 21 and 23-24 are to an isolated and purified protective HMW2 protein comprising SEQ ID NO:41.

Group ZZ, claims 21 and 23-24 are to an isolated and purified protective HMW2 protein comprising SEQ ID NO:45.

Group AB, claims 21 and 23-24 are to an isolated and purified protective HMW2 protein comprising SEQ ID NO:45.

Group AC, claims 21 and 23-24 are to an isolated and purified protective HMW2 protein comprising SEQ ID NO:49.

Group AD, claims 21 and 23-24 are to an isolated and purified protective HMW2 protein comprising SEQ ID NO:53.

Group AE, claims 21 and 23-24 are to an isolated and purified protective HMW2 protein comprising SEQ ID NO:57.

Group AF, claims 21 and 23-24 are to an isolated and purified protective HMW2 protein comprising SEQ ID NO:61.

Group AG, claims 21 and 23-24 are to an isolated and purified protective HMW2 protein comprising SEQ ID NO:65.

Group AH, claims 21 and 23-24 are to an isolated and purified protective HMW2 protein comprising SEQ ID NO:69.

Group AI, claims 21 and 23-24 are to an isolated and purified protective HMW2 protein comprising SEQ ID NO:73.

Group AJ, claims 25-29 and 30-31 are drawn to an immunogenic composition comprising SEQ ID NO:25 or 26.

Group AK, claims 25-29 and 30-31 are drawn to an immunogenic composition comprising SEQ ID NO:27 or 28.

Group AL, claims 25-29 and 30-31 are drawn to an immunogenic composition comprising SEQ ID NO:29 or 30.

Group AM, claims 25-29 and 30-31 are drawn to an immunogenic composition comprising SEQ ID NO:31 or 32.

Group AN, claims 25-29 and 30-31 are drawn to an immunogenic composition comprising SEQ ID NO:33 or 34.

Group AO, claims 25-29 and 30-31 are drawn to an immunogenic composition comprising SEQ ID NO:35 or 36.

Group AP, claims 25-29 and 30-31 are drawn to an immunogenic composition comprising SEQ ID NO:37 or 38.

Group AQ, claims 25-29 and 30-31 are drawn to an immunogenic composition comprising SEQ ID NO:39 or 40.

Group AR, claims 25-29 and 30-31 are drawn to an immunogenic composition comprising SEQ ID NO:41 or 42.

Group AS, claims 25-29 and 30-31 are drawn to an immunogenic composition comprising SEQ ID NO:43 or 44.

Group AT, claims 25-29 and 30-31 are drawn to an immunogenic composition comprising SEQ ID NO:45 or 46.

Group AU, claims 25-29 and 30-31 are drawn to an immunogenic composition comprising SEQ ID NO:47 or 48.

Group AV, claims 25-29 and 30-31 are drawn to an immunogenic composition comprising SEQ ID NO:49 or 50.

Group AW, claims 25-29 and 30-31 are drawn to an immunogenic composition comprising SEQ ID NO:51 or 52.

Group AX, claims 25-29 and 30-31 are drawn to an immunogenic composition comprising SEQ ID NO:53 or 54.

Group AY, claims 25-29 and 30-31 is drawn to an immunogenic composition comprising SEQ ID NO: 55 or 56.

Group AZ, claims 25-29 and 30-31 are drawn to an immunogenic composition comprising SEQ ID NO:57 or 58.

Group BA, claims 25-29 and 30-31 are drawn to an immunogenic composition comprising SEQ ID NO:59 or 60.

Group BC, claims 25-29 and 30-31 are drawn to an immunogenic composition comprising SEQ ID NO:61 or 62.

Group BD, claims 25-29 and 30-31 are drawn to an immunogenic composition comprising SEQ ID NO:63 or 64.

Group BE, claims 25-29 and 30-31 are drawn to an immunogenic composition comprising SEQ ID NO:65.

Group BF, claims 16-17 and 32-36 are drawn to a method of the production of a HMW protein of a nontypeable strain of *Haemohpilus* comprising transformed *E.coli*.

2. The inventions listed as Groups A-BF do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups A-L has a different special technical feature when compared to the nucleic acid molecule, plasmid vector, and HMW1 or HMW2 proteins because the recited components of the vector are the special technical features. Theses special technical features are comprised within the structural differences of the molecule which comprise a promoter operatively coupled to a modified operon wherein the gene of the operon contains only a nucleic acid sequence comprising SEQ ID NO:27, 28, 31, 32, 36, 37, 40, 41, 44, 45, 48, 49, 52, 53, 56, 57, 60, 61, 64, 65, 68, 69, 72, or 73. Groups M-GG are drawn to a nucleic acid molecule encoding a HMW protein having a variety of different sequences, thus the sequences are the special technical feature. The special technical feature of Group HH is found within the plasmid vector comprising the T7 promoter, a cloning site for insertion of a nucleic acid molecule and the portion B and C of the operon of a non-typeable *Haemophilus* strain. Groups II-UU are drawn to HMW1 or HMW2 proteins comprising one of 12 sequences. The immunogenic compositions recited in groups AJ-BE can be used with other methods. For instance, the composition can be used in a method to induce an immune response or with a method of administration. Therefore, the composition's special technical feature is comprised within the composition and not within the methods; therefore the groups lack the same or corresponding technical feature.

Groups A-GG and II-BE are all drawn to a plurality of disclosed patentably distinct nucleic acid sequences comprising materially different nucleic or amino acids as evidence by separate SEQ ID Numbers provided within the specification. The separate nucleic acid sequences bear distinct structural or biochemical properties. Therefore, each disclosed patentably distinct nucleic or amino acid sequence is considered a separate invention. The nucleic acid molecules, vectors, plasmid and proteins as defined by groups A-GG and II-BE are unrelated as they utilize different sequences, which demonstrates that each product has a different function and mode of operation. Each invention performs its function using structurally and functionally divergent material. The groups are directed to different molecules which are distinct physically, structurally, and functionally and are therefore patentably distinct, each group from the other, and one sequence is not required to practice the other. Each group comprises separate and distinct nucleic acid sequences that do not share a substantial structural feature disclosed as being essential to the utility of the invention. Therefore, each method is unrelated. For these reasons the groups are patentably distinct.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing which inventions are obvious variants of each other or clearly admit on the record which inventions are obvious variants of each other. If the inventions are deemed obvious variants of each other, then if the examiner finds one of the inventions unpatentable over the prior art, the evidence submitted by applicant or admission of

record by applicant may be used in a rejection under 35 U.S.C. §103(a) of the other inventions.

Group BF, is drawn to an unrelated invention to group A-BE because its use, function and effect are patentably distinct in comparison to the other groups. Moreover, group BF is unrelated and does not share a special technical feature because the method has a separate and distinct purpose with separate and distinct final outcomes. Therefore, there is no corresponding special technical feature between the groups A-BE and BF.

3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
September 25, 2005